

Remarks

Claims 1, 19, 26, 29, 31-33, and 42-45 were rejected under 35 U.S.C. §102(b) as being anticipated by the Corcuff et al. “In vivo Vision of the Human Skin with the Tandem Scanning Microscope,” *Dermatology* 1993, No. 186, pp. 50-54 (“Corcuff article”). This rejection is respectfully traversed. Claim 1 describes means for maintaining an area of the skin tissue under stress by application of force against a plate, and an imaging head, coupled to the maintaining means, capable of producing one or more images representing optically formed sections of the stressed skin tissue from light returned through the plate from focused light under the surface of said skin tissue. The Corcuff article cannot anticipate Claim 1 where it fails to describe any plate through which light is returned from the tissue. It is believed that the microscope of the Corcuff article is the same one described in U.S. Patent No. 5,719,700, which shows the contact endpiece of the Corcuff article in such detail that it clearly cannot anticipate Claim 1, and is not even suggestive of Claim 1.

The Corcuff patent shows in FIGS. 1 and 3 and describes at column 1, lines 52-56, a contact endpiece with a central opening and linkage to the skin about the central opening. The Corcuff patent teaches at column 3, lines 39-46, that the contact endpiece (11) has,

“a sleeve including a base 12 provided with a circular central opening 13 having a diameter at least equal to and preferably exceeding the exit diameter of the lens 2...The contact endpiece 11 is intended to bear by the lower plane face of its base 12 against the skin P and to be *linked to the skin the annular region surrounding the opening 13.*” (italic added).

As shown in FIGS. 1 and 3, a washer (14) is provided having a central hole (14a) with a diameter at least equal to opening 13 for linkage of the endpiece (11) to the skin (see column 3, lines 47-50). Thus, maintaining an opening, i.e., the central opening (13) and hole (14a) of the washer, between the lens and the tissue being imaged is a feature of the Corcuff patent, and it is through this opening that the lens images tissue. FIGS. 1 and 3 only show a drop (21) of liquid in this opening between lens (2) and the surface of the skin in Corcuff (see column 4, lines 18-23). The Corcuff patent teaches that this drop (21) has a refractive index substantially equal to the surface layer of the skin in order to suppress the interfaces and reflections. Accordingly, there is no plate in the Corcuff patent capable of application of force to tissue through which such tissue is illuminated and light is received, as called for in Claim 1. Corcuff's opening between its lens and the surface of tissue clearly is not comparable to the claimed plate, since base (12) defines central opening (13) through which imaging of skin (P) takes place in Corcuff (See, for example, illustrated light rays through liquid (21) in opening (13) of FIG. 1).

Accordingly, each and every element of Claim 1 is not disclosed in the Corcuff patent, or the Corcuff article. For similar reasons, Claims 26 and 43 are also not anticipated by the Corcuff patent or article. Thus, Applicant requests the 35 U.S.C. §102 rejection of Claims 1, 26, and 43 in view of the Corcuff article, and of their respective dependent Claims 19, 29, 31-33, 42, and 44-45 be withdrawn.

Claims 1, 2, 8, 19, 26-37, and 42-46 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,146,923 (Dhawan). Claim 1, as amended, describes an imaging head capable of producing one or more images of optically formed sections of the stressed skin tissue from light returned through a plate from focused light under the surface of the skin tissue. Dhawan describes a nevoscope which uses a still or video camera (9) of Fig. 1 or camera 74 of Fig. 5 to record images of tissue (see column 7, lines 8-10). A still or video camera cannot provide an image of a section through tissue from light returned from focused light under the tissue surface, but rather provides an image of the tissue surface, or an image of a volume of tissue transilluminated from the surface to a depth. It is the Examiner's position that Fig. 3 shows that Dhawan can image "a section of tissue from light returned from focused light under the surface of the tissue" (see page 3, lines 3-5, of the Office Action dated November 19, 2004). The camera (9 and 74) of Dhawan captures an image of the tissue but cannot optically discriminate any section under the surface. Accordingly, Dhawan relies on computer tomography to obtain sections (see top paragraph of column 3, and a computer-reconstructed cross-section of tissue at column 5, and especially, column 5, at lines 11-16 and 53-57). Computer-reconstructed sections are not optically formed, as called for in Claim 1. Clearly, if Dhawan was capable of providing images of optically formed sections, why would it describe use of computer reconstruction to generate an image of a cross-section? Therefore, Claim 1 and any dependent claims thereupon are not anticipated by Dhawan.

Claim 26 describes imaging stressed tissue from light returned from a scanned focal spot through the tissue to provide an image of a section. Dhawan describes a nevoscope having a still or video camera (9) which does not operate by scanning a focal spot through tissue. If it did, it would not be a still or video camera. Fig. 3 of Dhawan does not show a scanned focal spot. Dhawan at best can image a tissue surface, or an image of a volume of tissue transilluminated from the surface to a depth. It is submitted that Dhawan requires computer reconstruction to obtain a cross-sectional image due to the fact that it is volume based imaging. Thus, Claim 26 and any dependent claims thereupon are not anticipated by Dhawan.

With respect to Claim 19, Dhawan shows no optical elements for confocal imaging, but only a still or video camera. Still or digital cameras cannot enable confocal imaging which optically sections tissue. Thus, Claim 19 cannot be anticipated by Dhawan. For reasons argued with respect to Claim 1, amended Claims 35 and 43 and their respective dependent Claims 36-37 and 44-46 are also not anticipated by Dhawan. Withdrawal of the rejection of Claims 1, 2, 8, 19, 26-36, and 42-46 as being anticipated by Dhawan is respectfully requested.

Claims 2, 6, 8, 27, 28, 30, 34-37, and 46 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Corcuff article in view of Dhawan. Claims 2, 6, 8, 27, 28, 30, and 46 depend on respective base Claims 1 and 26. As argued earlier, the Corcuff article neither describes, nor suggests maintaining an area of any tissue under stress by application of force against a plate, as called for in base Claims 1 and 26. No plate is described or suggested in the Corcuff et al. article or Corcuff patent. Dhawan is a nevoscope which, as argued earlier, is not capable of producing one or more images representing optically formed sections of the stressed tissue from light returned from focused light under the surface of the tissue. Dhawan's inverted cup shaped housing 44 would not obviously be used in the Corcuff patent since it would negatively impact the performance of Corcuff. The Corcuff patent is believed to show the endpiece of the Corcuff article in more detail, and the Corcuff patent at column 4, lines 11-17, states that the endpiece allows variation in the depth of imaging by varying the elasticity of the skin tissue. As a result, if a plate were placed in the central opening of the Corcuff endpiece, this would negatively affect the ability to vary the depth between the lens and the tissue surface. One skilled in the art would not modify a device in a manner which would negatively impact its operation as taught by the reference. Moreover, the fact that the Corcuff patent relies on its central opening (13), rather than a plate, to image tissue, teaches away from using a plate in that opening. Thus, it cannot be obvious where there is no motivation for combination, and the Corcuff patent actually teaches away from such combination with Dhawan. For similar reasons, Claims 35-36 are patentable over the Corcuff article and Dhawan. Accordingly, Applicant requests the 35 U.S.C. §103(a) rejection of Claims 2, 6, 8, 27, 28, 30, 34-36, and 46 be withdrawn.

Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over the Corcuff article in view of Dhawan, and further in view of the Jester et al. article "In Vivo, Real-time Control Imaging" in the Journal of Electron Microscopy Techniques, Vol. 18, No. 1 (1991). Claim 3 depends on Claim 1, which for reasons argued earlier is patentable over the Corcuff

article and Dhawan, either alone or in combination. Withdrawal of the rejection of Claims 3 is thus requested.

Claims 20 and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Corcuff article in view of Dhawan, and further in view of Jester et al. The Corcuff article and Dhawan both fail to describe or suggest the first and second moving means of Claim 20, and the translating means of Claim 23. Moreover, as argued earlier, one skilled in the art would not combine the Corcuff article with Dhawan, since the Corcuff Patent to which the Corcuff article relates teaches away from such combination. Also, one skilled in the art would not combine Dhawan and Jester et al. Dhawan relates to a handheld portable nevoscope which receives a raised tissue specimen in its inverted cup housing (44) (see Abstract, FIG. 1, and column 7, lines 54-55 of Dhawan). Connecting the Dhawan nevoscope to the x,y,z table of Jester et al. (see FIG. 2 of Jester et al.) would obviate Dhawan both being handheld and portable (see, Abstract lines 2-3 of Dhawan). Moreover, no need is present for a x,y,z table in Dhawan since a specimen in Dhawan's nevoscope is positionally oriented in the nevoscope by virtue of the specimen's placement in the inverted cup housing (44), as clearly evident by FIG. 1 of Dhawan. Therefore, Dhawan already provides by its design proper alignment to tissue and thus no motivation for adding alignment by an x,y,z table of Jester et al. is present, especially where it prevents Dhawan from being portable as taught by Dhawan. One skilled in the art would not add an element which obviates the teaching of a design. Moreover, Jester et al. fails to show the platen of Claims 20 and 23 having an orifice for stabilizing tissue. Thus, Claims 20 and 23 are patentable over Dhawan, Corcuff article, and Jester et al., either alone or in combination, and withdrawal of their rejection is requested.

Claims 3, 20, and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Dhawan in view of the Jester et al. Dhawan describes a nevoscope which for reasons argued above would not be combined with Jester et al. by one skilled in the art. There is no need for complex alignment of Jester et al. when Dhawan by its design assures proper alignment. Accordingly, Applicant requests the rejection of Claims 3, 20 and 23 in view of Dhawan and Jester et al. be withdrawn.

Claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable over Dhawan. Claim 6 depends on base Claim 1, which for reasons argued earlier is patentable over Dhawan. Dhawan further lacks the Claim 6 means for translating an imaging head in the claimed integrated assembly of Claim 1. It is the Examiner's position that "Dhawan discloses means for moving the imaging head with respect to the orifice in that the camera can be inserted into the

device" (page 6, lines 19-21, of the Office Action of November 19, 2004). Mere insertion of a video or still camera (9) in an eyepiece (10) of Dhawan is not comparable to translating an imaging head. Dhawan does not describe or suggest any movement of its camera (9) once inserted in the opening of housing (22). Nevertheless, such movement is not obvious where FIG. 1 of Dhawan shows the end of camera (8) of a dimension fitting the opening of housing (28) at lens (12). If it is the Examiner's position that the camera's insertion represents the translation means of Claim 6, then it necessarily occurs when camera (9) is not integrated with housing (28). As a result, when the Examiner contended translation takes place not all of base Claim 1 limitations are met at that time since Dhawan cannot be considered as having the claimed integrated assembly between its camera (9) and housing (28). Clearly, one cannot take a position with a dependent claim which conflicts with a previous position taken with the base claim. Thus, Applicant requests the rejection of Claim 6 be withdrawn.

Claims 21 and 22 are allowable but objected to as being dependent on rejected claims. Applicant believes that dependent Claims 21 and 22 are allowable along with their base Claim 20.

Claim 37 has been canceled without prejudice in light of the Amendment of its base Claim 36.

Claims 47-48 have been added to the Application. Claims 47-48 are patentable over the Corcuff article, the Corcuff Patent, Dhawan, Jester et al., either alone or in combination.

A Third Supplemental Information Disclosure Statement is enclosed.

A Combined Amendment and Petition for Extension of Time is enclosed with a check in the amount of \$475.00 for the required petition fee and additional claim fee.

Respectfully submitted,

Dated: April 19, 2005



Kenneth J. LuKacher
Attorney for Applicant
Registration No. 38,539

South Winton Court
3136 Winton Road South, Suite 204
Rochester, New York 14623
Telephone: (585) 424-2670
Facsimile: (585) 424-6196

Enclosures: Combined Amendment and Petition for Extension of Time Transmittal with check for \$475.00; Third Supplemental Information Disclosure Statement.